UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,270	09/29/2003	Christopher S. de Voir	117163.00092	3098

21324   7590   05/11/2006

HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

EXAMINER
DATSKOVSKIY, SERGEY

ART UNIT	PAPER NUMBER
2121	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	10/674,270	DE VOIR ET AL.
	Examiner	Art Unit	
	Sergey Datskovskiy	2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>23 April 2004</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>24 May 2004</u> is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1.   Claims 1-18 have been submitted for examination.

2.   Claims 1-18 have been rejected.

Drawings

3.   The drawings are objected to because the unlabeled rectangular boxes shown in the Figure 1 should be provided with descriptive text labels. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.   A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 15 of copending Application No. 10/674,280, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the application being examined are broader than the claims of the copending application. Specifically, claim 14 of the copending limitation contains all limitations of claim 1 of the current application, with an addition of an "updating unit". Furthermore, the limitation of claim 2 of current application is the same as the limitation of claim 15 of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4.   Claims 1-3 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Esteller et al. (US Patent No. 6,594,524).

Claim 1

. Esteller teaches an apparatus for the classification of physiological events (col. 5, lines 42-47), comprising:

a signal input for the input of a physiological signal representing or constituting a physiological event (col. 9, lines 34-36); and

a classification unit for classifying the physiological signal on the basis of its signal shape (Figs. 1, 3, Intelligent Data Processing Unit 200; col. 9, lines 19-28), the classification unit comprising:

a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation (Fig. 4, preprocessing 210 and feature extraction; col. 9, lines 20-25; col. 20, lines 26-36); and

a probabilistic neural network (Fig. 32, col. 36, lines 43-50) which is connected to the transformation unit to receive the values (Fig. 4, analysis/classification 260; col. 10, lines 37-44) and which contains a number of event classes which represent physiological events and which in turn are each represented by a set of comparative values (col. 36, lines 30-40), which probabilistic neural network is adapted on the basis of the comparison of the values with the comparative values to effect an association of the physiological signal represented by the values with one of the event classes (col. 37, lines 10-17).

Claim 2

Esteller teaches the apparatus of claim 1, wherein: the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets (col. 28, lines 21-44).

Claim 3

Esteller teaches the apparatus of claim 2, wherein: the comparative values of the probabilistic neural network are based on a transformation procedure in which the same wavelets and the same transformation rule as in the transformation unit are used (Fig. 32, col. 37, lines 10-17; inputs of the neural network come from the outputs of transformation unit, therefore said comparative values are based on the transformation procedure).

Claim 13

Esteller teaches the apparatus of claim 1, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (col. 13, lines 39-44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5.   Claims 4-9, 11-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller et al. (US Patent No. 6,594,524) in view of Echauz et al. (US Patent No. 6,678,548).

Claims 4, 11 and 12

Regarding claim 4, Esteller teaches the apparatus of claim 3, wherein the probabilistic neural network further comprises: at least one ascertaining unit for determining association probabilities of the physiological signal with the event classes on the basis of the comparison of the values with the comparative values of the respective event class and for outputting the ascertained association probabilities (Fig. 32, col. 37, lines 11-20);

Esteller does not expressly teach selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability (it is disclosed in Fig. 32 as competitive layer, but without a detailed explanation).

However, Echauz teaches selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability (col. 26, lines 36-39 mention competitive layer as a maximum selector; see also col. 18, lines 53-66).

Esteller and Echauz are analogous art since they are both directed to different aspects of the same invention. At the time of the invention, it would have been obvious

to a person of ordinary skill in the art to include the details on implementation of a

probabilistic neural network from Echauz and combine it with the probabilistic neural

network of Esteller. One would be motivated to do it in order to find the details of how

the probability of having a seizure is estimated (Esteller, col. 10, lines 47-49).

Therefore, it would have been obvious to modify Esteller in view of Echauz by including

the details of implemented neural network in the apparatus for predicting seizures.

Claims 11 and 12 are rejected on the same basis as claim 4, having the same

limitations but different scope.

Claim 5

Esteller teaches the apparatus of claim 4, wherein: two or more sets of

comparative values representing the same event class are present for at least one

event class (col. 13, lines 39-44).

Claim 6

Esteller teaches the apparatus of claim 5, wherein: the ascertaining unit is

adapted to determine a plurality of association probabilities for each event class which

has two or more sets of comparative values representing the same event class (Fig. 32,

T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event

classes which have two or more sets of comparative values representing the same

event class, it forms average values of the corresponding association probabilities and

upon extraction of the highest association probability uses the average values instead of

the individual values (Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T_1 and T_2 form probabilities P_1 and P_2 correspondingly).

Claim 7

Esteller teaches the apparatus of claim 6, further comprising: an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit connected upstream of the transformation unit (col. 10, lines 5-15; col. 20, lines 26-36).

Claim 8

Esteller teaches the apparatus of claim 7, wherein: in those event classes which include two or more sets of comparative values representing the same event class, the sets of comparative values correspond to different offsets in the centering of the centered physiological signal (col. 24, lines 62-65; col. 32, lines 62-67).

Claim 9

Esteller teaches an implantable medical device characterized in that it is provided with an apparatus for the classification of physiological events as set forth in claim 8 (col. 3, lines 33-35).

Claim 14

Esteller teaches the apparatus of claim 11, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (col. 13, lines 39-44).

Claim 15

Esteller teaches the apparatus of claim 12, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (col. 13, lines 39-44).

Claim 16

Esteller teaches the apparatus of claim 14, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and upon extraction of the highest association probability uses the average values instead of the individual values (Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T_1 and T_2 form probabilities P_1 and P_2 correspondingly).

Claim 17

Esteller teaches the apparatus of claim 15, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and upon extraction of the highest association probability uses the average values instead of the individual values (Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T_1 and T_2 form probabilities P_1 and P_2 correspondingly).

Claim 18

Esteller teaches the apparatus of claim 6, further comprising: an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit, the adjusting unit being connected upstream of the transformation unit (col. 10, lines 5-15; col. 20, lines 26-36).

6.   Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esteller

et al. (US Patent No. 6,594,524) in view of Echauz et al. (US Patent No. 6,678,548),

and further in view of Igel et al. (US Patent No. 6,192,273).

Claim 10

Esteller teaches the implantable medical device of claim 9, wherein (col. 3, lines

33-35; disclosed device is capable of doing electric pacing, see col. 14, lines 57-60).

Esteller does not expressly teach that the implantable medical device is in the

form of a cardiac pacemaker or defibrillator.

Igel teaches the implantable medical device is in the form of a cardiac

pacemaker or defibrillator (Fig. 1, alarm/pacing system 90; col. 3, lines 29-34).

Esteller and Igel are analogous art since they are both implantable devices

capable of doing electric pacing.   At the time of the invention, it would have been

obvious to a person of ordinary skill in the art to include the classifier from Esteller and

combine it with the implantable device from Igel by using it as a neural network classifier

(Igel, col. 7, lines 40-44).   Such combination would be reasonable, due to probability

neural network being suitable for classification problems and having a straightforward

design (Esteller, col. 36, lines 43-46).   Therefore, it would have been obvious to modify

Esteller in view of Igel by using the classifier based on a probabilistic neural network in

the heart rhythm classifier with an implanted pacemaker.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Leong et al. (US Patent No. 5,280,792) teaches a method and system for automatically classifying intracardiac electrograms. Nguyen et al. (US Patent No. 6,105,015) teaches a wavelet-based hybrid neurosystem for classifying a signal or an image represented by the signal in a data system. Snyder et al. (US Patent No. 6,287,328) teaches using neural network with a defibrillator. Litt et al. (US Patent No. 6,658,287) teaches a method and apparatus for predicting the onset of seizures based on features derived from signals indicative of brain activity. Wilson (US Patent No. 6,735,467) teaches method and system for detecting seizures using electroencephalograms. Addison et al. (US App. No. 2005/0070774) teaches a wavelet-based analysis of pulse oximetry signals. Lange (US Patent No. 6,898,582) teaches method and apparatus for extracting low SNR transient signals from noise. D'Alessandro et al. (Biomedical Engineering, IEEE Transactions on, May 2003, Volume: 50, Issue: 5, page(s): 603-615) teaches "Epileptic Seizure Prediction Using Hybrid Feature Selection Over Multiple Intracranial EEG Electrode Contacts: A Report of Four Patients".

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sergey Datskovskiy whose telephone number is (571)

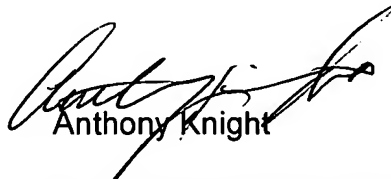272-8188. The examiner can normally be reached on Monday-Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Knight, can be reached on (571) 272-3687. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S.D.   Anthony Knight

Assistant examiner   Supervisory Patent Examiner

A.U. 2121   Technology Center 2100